UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,717	09/01/2000	Gabriel Villafane	EGYP 3.0-008	5779

530 7590 06/03/2003

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER
COOK, REBECCA

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/653,717	VILLAFANE ET AL.	
	Examiner	Art Unit	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,12-15,18,19,21-28,31-41,44-46 and 49-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-, 12-15, 18-19, 21-28, 31-41, 44-46, 49-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 45 and 46 have been renumbered as claims 56 and 57.

ok p4 ok p11

Claims 41 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' arguments have been considered but are not persuasive. While support is seen on page 8 for the rate of 0.2 mg in claim 41, no support is seen for 3 mg per day per kg. Also, while support is seen on page 7 for the rate of 93 mg in claim 45, no support is seen on page 7or 11 for the rate of 160 mg per day.

In view of applicants' arguments the remaining earlier rejections under 35 USC 11, paragraph one are withdrawn.

Claims 10, 12-14, 18-19, 21-28, 31-41, 44-46, 49-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of nicotine or a derivative thereof for producing a drug for continuous or progressive administration of 0.2 mg to 5 mg per day per kilogram of body with in a man (human) when being administered simultaneously with L-DOPA in a dose a t least 30% lower than the effective dose when L-DOPA is administered alone, does not reasonably

provide enablement for any and all doses of nicotine or L_DOPA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Page 4, lines 1-8, discloses the nature of the instant invention.

Claims 10, 12-14, 44-46, 50-55, 56-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The word "progressive" in claims 10, 44, 50, 53 and 55 is confusing and is not defined in the specification. Applicants' argues that the meaning is indicated on pages 4 and 5 and corresponds to a staged increase in dosage and that there is no requirement that each term be expressly defined as long as those skilled in the art would understand what is claimed when the claim is read in light of the specification. This is not persuasive. On pages 4 and 5 the specification discloses that the drug protocol involves a gradual increase followed by stabilized doses. Furthermore, no such meaning is found in Webster's II New Riverside University Dictionary, 1984, page 940, which defines "progressive" as "1. moving forward; advancing. 2, proceeding in steps. 3. promoting or favoring political or social reform; liberal. 4. of or belonging to a Progressive Party. 5. of, pertaining to, or influenced by a theory of education...6. of or denoting a tax system. 7 Pathol. continuously spreading or increasing in severity. 8. indicating a verb form..."

In claims 56 and 57 the intended recipient is not recited. Amending the claims to "comprising administering to said human mammal" will overcome this rejection.

In view of applicants' arguments canceling of claim 11 the remaining earlier arguments under 35 USC 112, paragraph two are withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10, 12-15, 18-19, 21-28, 31-41, 44-46, 49-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domino et al or applicants' admissions for the reasons given in Paper No. 12.

Applicants' argument that Domino does not suggest altering the dosage of L-DOPA to limit its side effects is not persuasive. The amount and dosage ranges are not recited in all of the independent claims. Furthermore, in the absence of a showing of unexpected results, once a method of using a composition is known it is within the skill of the artisan to determine the optimum amounts.

Applicants' argue that the treatment proposed in Domino et al does not include a method to improve the functionality of D1 and D2 dopaminergic receptors. This is not persuasive. Improving the functionality of D1 and D2 dopaminergic receptors is the mechanism by which the method works in the treatment of neurodegenerative disease. It would be obvious to one of ordinary skill in the art that there would be improvement in

the functionality of the receptors involved in the neurodegenerative disease when the disease responds favorably to treatment with specific compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

REBECCA COOK
PRIMARY EXAMINER
GROUP ~~1200~~ 1614

June 2, 2003